75% ETHYL ALCOHOL GEL SANITIZER- alcohol liquid Midland Products LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

75% Ethyl Alcohol Gelled Formula - CONSUMER

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

Active Ingredient(s)

Alcohol 80% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Warnings

For external use only. Flammable. Keep away from heat or flame

Do not use

- in children less than 2 months of age
- on open skin wounds

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel

| NDC: 77136-500-75 | Drug Facts | |
|------------------------------------|---|-----------|
| | Active Ingredient(s) | Purpose |
| | Ethyl Alcohol 75% v/v | Antisept |
| | Use(s) | |
| Alcohol Antiseptic 75% | Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not avail | able. |
| | Warnings | |
| | For external use only. Flammable. Keep away from heat or flame | |
| | Do not use | |
| | • in children less than 2 months of age | |
| Hand Canitinan Cal | • on open skin wounds | |
| Hand Sanitizer Gel | When using this product keep out of eyes, ears, and mouth. In case of contact with eye, rinse eyes thoroughly with | water. |
| | Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition. | |
| | Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. | |
| | Directions | |
| MIDLAND | Place enough product on hands to cover all surfaces. Rub hands together until dry. | |
| PRODUCTS | Supervise children under 6 years of age when using this product to avoid swallowing. | |
| | Other Information | |
| | • Store between 15-30C (59-86F) | |
| | Avoid freezing and excessive heat above 40C (104F) | |
| Vol: 275 gal (1040.98L) | Inactive Ingredients: Water, Acrylates Copolymer, Fragrance, Aminomethyl Propanol | |
| MADE IN USA | Manfufactured for: | |
| | Midland Products LLC 18600 Graphic Ct. | |
| | Tinley Park, IL 60477 | |
| | Phone: 708-444-8200 | |
| NDC: 77136-500-55 | Drug Facts | ĝΧ |
| | Active Ingredient(s) | Purpose |
| | Ethyl Alcohol 75% v/v | Ant isept |
| | Use(s) | |
| Alcohol Antiseptic 75% | Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not avail | ahle |
| Alcohol Alltiseptic 73/0 | Warnings | uore. |
| • | For external use only. Flammable. Keep away from heat or flame | |
| | Do not use | |
| | • in children less than 2 months of age | |
| 11 1 C | • on open skin wounds | |
| Hand Sanitizer Gel | When using this product keep out of eyes, ears, and mouth. In case of contact with eye, rinse eyes thoroughly with water. | |
| | Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition. | |
| | Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. | |
| | Directions | |
| MIDI AND | • Place enough product on hands to cover all surfaces. Rub hands together until dry. | |
| PRODUCTS | Supervise children under 6 years of age when using this product to avoid swallowing. | |
| | Other Information | |
| | •Store between 15-30C (59-86F) | |
| | • Store between 15-30C (59-86F) | |
| | Store between 15-30C (39-86F) Avoid freezing and excessive heat above 40C (104F) | |
| Vol: 55 gal (208.19L) | 100 pt 100 min 110 min 100 pt | |
| Vol: 55 gal (208.19L) MADE IN USA | Avoid freezing and excessive heat above 40C (104F) Inactive Ingredients: Water, Acrylates Copolymer, Fragrance, Aminomethyl Propanol Manfufactured for: | |
| Vol: 55 gal (208.19L) MADE IN USA | Avoid freezing and excessive heat above 40C (104F) Inactive Ingredients: Water, Acrylates Copolymer, Fragrance, Aminomethyl Propanol Manfufactured for: Midland Products LLC | |
| Vol: 55 gal (208.19L) MADE IN USA | Avoid freezing and excessive heat above 40C (104F) Inactive Ingredients: Water, Acrylates Copolymer, Fragrance, Aminomethyl Propanol Manfufactured for: | |

| N DC: 77136-500-05 | Drug Facts | |
|---------------------------------------|--|------------------|
| | Active Ingredient(s) | Purpose |
| | Ethyl Alcohol 75% v/v | Antisep |
| | Use(s) | |
| Alcohol Antiseptic 75% | Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available. | |
| Alcohol Alltiscptic 7570 | Warnings | |
| | For external use only. Flammable. Keep away from heat or flame | |
| | Do not use | |
| | in children less than 2 months of age on open skin wounds | |
| Hand Sanitizer Gel | When using this product keep out of eyes, ears, and mouth. In case of contact with eye, rinse eyes thoroughly with water | |
| Haria Samitizer Ger | Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition. | |
| | Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. | |
| | Directions | |
| MIDLAND | • P lace enough product on hands to cover all surfaces. Rub hands together until dry. | |
| PRODUCTS | • Supervise children under 6 years of age when using this product to avoid swallowing. | |
| | Other Information | |
| | • Store between 15-30C (59-86F) | |
| V 1 = 1 (40 co) | Avoid freezing and excessive heat above 40C (104F) | |
| Vol: 5 gal (18.92L) ADE IN USA | Inactive Ingredients: Water, Acrylates Copolymer, Fragrance, Aminomethyl Propanol | |
| ADE IN USA | Manfufactured for: Midland Products LLC | |
| 8888 | 18600 Graphic Ct. | |
| | Tinley Park, IL 60477 | |
| | Phone: 708-444-8200 | Tiv. |
| NDC: 77136-500-10 | Drug Facts | |
| | Active Ingredient(s) | Purpos |
| | Ethyl Alcohol 75% v/v | Ant isep |
| | Use(s) | |
| Alcohol Antiseptic 75% | Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available. | |
| Alcohol Alltiscptic 73/0 | Warnings | |
| | For external use only. Flammable. Keep away from heat or flame | |
| | Do not use | |
| | • in children less than 2 months of age | |
| Hand Sanitizer Gel | on open skin wounds When using this product keep out of ever pays, and mouth. In case of contact with ever rings ever thoroughly with water. | |
| nanu Sannuzei Gei | When using this product keep out of eyes, ears, and mouth. In case of contact with eye, rinse eyes thoroughly with water | r. |
| | Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. | |
| | Directions | |
| | Place enough product on hands to cover all surfaces. Rub hands together until dry. | |
| WIIDI VANID | | |
| PRODUCTS | Supervise children under 6 years of age when using this product to avoid swallowing. | |
| PRODUCTS | COURT AN INC. TOUR | |
| PRODUCTS | Supervise children under 6 years of age when using this product to avoid swallowing. Other Information Store between 15-30C (59-86F) | |
| PRODUCTS | Other Information | |
| Vol: 1 gal (3.78L) | Other Information *Store between 15-30C (59-86F) | |
| | Other Information Store between 15-30C (59-86F) Avoid freezing and excessive heat above 40C (104F) Inactive Ingredients: Water, Acrylates Copolymer, Fragrance, Aminomethyl Propanol Manfuractured for: | |
| | Other Information •Store between 15-30C (59-86F) •Avoid freezing and excessive heat above 40C (104F) Inactive Ingredients: Water, Acrylates Copolymer, Fragrance, Aminomethyl Propanol Manfurfactured for: Midland Products LLC | |
| | Other Information Store between 15-30C (59-86F) Avoid freezing and excessive heat above 40C (104F) Inactive Ingredients: Water, Acrylates Copolymer, Fragrance, Aminomethyl Propanol Manfuractured for: | |
| | Other Information *Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F) Inactive Ingredients: Water, Acrylates Copolymer, Fragrance, Aminomethyl Propanol Manfufactured for: Midland Products LLC 18600 Graphic Ct. | |
| MADE IN USA | Other Information *Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F) Inactive Ingredients: Water, Acrylates Copolymer, Fragrance, Aminomethyl Propanol Manfufactured for: Midland Products LLC 18600 Graphic Ct. Tinley Park, IL 60477 Phone: 708-444-8200 | |
| | Other Information *Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F) Inactive Ingredients: Water, Acrylates Copolymer, Fragrance, Aminomethyl Propanol Manfufactured for: Midland Products LLC 18600 Graphic Ct. Tinley Park, IL 60477 Phone: 708-444-8200 Drug Facts | Purnos |
| MADE IN USA | Other Information *Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F) Inactive Ingredients: Water, Acrylates Copolymer, Fragrance, Aminomethyl Propanol Manfufactured for: Midland Products LLC 18600 Graphic Ct. Tinley Park, IL 60477 Phone: 708-444-8200 Drug Facts Active Ingredient(s) | 100000 |
| MADE IN USA | Other Information *Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F) Inactive Ingredients: Water, Acrylates Copolymer, Fragrance, Aminomethyl Propanol Manfufactured for: Midland Products LLC 18600 Graphic Ct. Tinley Park, IL 50477 Phone: 708-444-8200 Drug Facts Active Ingredient(s) Ethyl Alcohol 75% v/v. | |
| NADE IN USA NDC: 77136-500-16 | Other Information *Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F) Inactive Ingredients: Water, Acrylates Copolymer, Fragrance, Aminomethyl Propanol Manfufactured for: Midland Products LLC 18600 Graphic Ct. Tinley Park, IL 50477 Phone: 708-444-8200 Drug Facts Active Ingredient(s) Ethyl Alcohol 75% v/v. Use(s) | Antisep |
| MADE IN USA | Other Information *Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F) Inactive Ingredients: Water, Acrylates Copolymer, Fragrance, Aminomethyl Propanol Manfufactured for: Midland Products LLC 18600 Graphic Ct. Tinley Park, IL 50477 Phone: 708-444-8200 Drug Facts Active Ingredient(s) Ethyl Alcohol 75% v/v | Antisep |
| NDC: 77136-500-16 | Other Information •Store between 15-30C (59-86F) •Avoid freezing and excessive heat above 40C (104F) Inactive Ingredients: Water, Acrylates Copolymer, Fragrance, Aminomethyl Propanol Manfufactured for: Midland Products LLC 18600 Graphic Ct. Tinley Park, IL 60477 Phone: 708-444-8200 Drug Facts Active Ingredient(s) Ethyl Alcohol 75% v/v. Use(s) Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available. Warnings | Antisep |
| NDC: 77136-500-16 | Other Information •Store between 15-30C (59-86F) •Avoid freezing and excessive heat above 40C (104F) Inactive Ingredients: Water, Acrylates Copolymer, Fragrance, Aminomethyl Propanol Manfurfactured for: Midland Products LLC 18800 Graphic Ct. Tinley Park, IL 60477 Phone: 708-444-8200 Drug Facts Active Ingredient(s) Ethyl Alcohol 75% v/v | Antisep |
| NADE IN USA NDC: 77136-500-16 | Other Information •Store between 15-30C (59-86F) •Avoid freezing and excessive heat above 40C (104F) Inactive Ingredients: Water, Acrylates Copolymer, Fragrance, Aminomethyl Propanol Manfufactured for: Midland Products LLC 18600 Graphic Ct. Tinley Park, IL 60477 Phone: 708-444-8200 Drug Facts Active Ingredient(s) Ethyl Alcohol 75% v/v. Use(s) Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available. Warnings | Antise |
| MADE IN USA NDC: 77136-500-16 | Other Information *Store between 15-30C (59-86F) Avoid freezing and excessive heat above 40C (104F) Inactive Ingredients: Water, Acrylates Copolymer, Fragrance, Aminomethyl Propanol Manfufactured for: Midland Products LLC 18600 Graphic Ct. Tinley Park, IL 60477 Phone: 708-444-8200 Drug Facts Active Ingredient(s) Ethyl Alcohol 75% v/v. Use(s) Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available. Warnings For external use only, Flammable. Keep away from heat or flame Do not use | Purpos:Ant isept |

Directions

Other Information

Hand Sanitizer Gel



MADE IN USA



• Store between 15-30C (59-86F) Avoid freezing and excessive heat above 40C (104F) Vol: 16 fl.oz (473.1 ml) Inactive Ingredients: Water, Acrylates Copolymer, Fragrance, Aminomethyl Propanol Manfufactured for: Midland Products LLC 18600 Graphic Ct. Tinley Park, IL 60477 Phone: 708-444-8200

When using this product keep out of eyes, ears, and mouth. In case of contact with eye, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

• Place enough product on hands to cover all surfaces. Rub hands together until dry.

 $\bullet \, \text{Supervise children under 6} \, \text{years of age when using this product to avoid swallowing}.$

| NDC: 77136-500-08 | Drug Facts | |
|-------------------------------|---|--|
| | Active Ingredient(s) Purpo | |
| | Ethyl Alcohol 75% v/v | |
| | Use(s) | |
| Alcohol Antiseptic 75% | Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available. | |
| Alcohol Alltiscptic 73/0 | Warnings | |
| | For external use only. Flammable. Keep away from heat or flame | |
| | Do not use | |
| Hand Sanitizer Gel | • in children less than 2 months of age | |
| | • on open skin wounds | |
| | When using this product keep out of eyes, ears, and mouth. In case of contact with eye, rinse eyes thoroughly with water. | |
| | Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition. | |
| | Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. | |
| | Directions | |
| MIDI AND | • Place enough product on hands to cover all surfaces. Rub hands together until dry. | |
| PRODUCTS | • Supervise children under 6 years of age when using this product to avoid swallowing. | |
| | Other Information | |
| | • Store between 15-30C (59-86F) | |
| | Avoid freezing and excessive heat above 40C (104F) | |
| Vol: 8 fl.oz (236.5 ml) | Inactive Ingredients: Water, Acrylates Copolymer, Fragrance, Aminomethyl Propanol | |
| IADE IN USA | Manfufactured for: | |
| | Midland Products LLC | |
| SOLON. | 18500 Graphic Ct. | |
| | Tinley Park, IL 60477 Phone: 708-444-8200 | |

Active Ingredient(s)

Alcohol Antiseptic 75%

Hand Sanitizer Gel



Vol: 2 fl.oz (59 ml)



| Ethyl Alcohol 75% v/v | Antiseptic | | | | |
|---|--------------------------|--|--|--|--|
| Use(s) | | | | | |
| Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and v | water are not available. | | | | |
| Warnings | | | | | |
| For external use only. Flammable. Keep away from heat or flame | | | | | |
| Do not use | | | | | |
| • in children less than 2 months of age | | | | | |
| • on open skin wounds | | | | | |
| When using this product keep out of eyes, ears, and mouth. In case of contact with eye, rinse eyes | sthoroughly with water. | | | | |
| Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition. | 60 - 90 | | | | |
| Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center ri | ght away. | | | | |
| Directions | | | | | |
| Place enough product on hands to cover all surfaces. Rub hands together until dry. | | | | | |
| • Supervise children under 6 years of age when using this product to avoid swallowing. | | | | | |
| Other Information | | | | | |
| • Store between 15-30C (59-86F) | | | | | |
| • Avoid freezing and excessive heat above 40C (104F) | | | | | |
| Inactive Ingredients: Water, Acrylates Copolymer, Fragrance, Aminomethyl Propanol | | | | | |
| Manfufactured for: | | | | | |
| Midland Products LLC | | | | | |
| 18600 Graphic Ct. | | | | | |
| Tinley Park, IL 60477 | | | | | |
| | | | | | |

59 mL NDC: 77136-500-02

236.5 mL NDC: 77136-500-08

473.1 mL NDC: 77136-500-16

3785.4 mL NDC: 77136-500-10

18927.1 mL NDC: 77136-500-05 208197.6 mL NDC: 77136-500-55

1040988.2 mL NDC: 77136-500-75

75% ETHYL ALCOHOL GEL SANITIZER

alcohol liquid

| Product Information | | | | |
|-------------------------|----------------|--------------------|---------------|--|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:77136-500 | |
| Route of Administration | TOPICAL | | | |
| | | | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|-----------------|
| ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL | 75 mL in 100 mL |

| Inactive Ingredients | | |
|---|-------------------|--|
| Ingredient Name | Strength | |
| METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (4500 MPA.S) (UNII: T967IEU43C) | 4.5 mL in 100 mL | |
| AMINOMETHYLPROPANOL (UNII: LU49E6626Q) | 0.14 mL in 100 mL | |
| WATER (UNII: 059QF0KO0R) | | |

| P | Packaging | | | | |
|---|-----------------------|--|-------------------------|-----------------------|--|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date | |
| 1 | NDC:77136- 500-02 | 59 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product | 04/15/2020 | | |
| 2 | NDC:77136- 500-08 | 236.5 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product | 04/15/2020 | | |
| 3 | NDC:77136- 500-16 | 473.1 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product | 04/15/2020 | | |
| 4 | NDC:77136 - 500-10 | 3785.4 mL in 1 JUG; Type 0: Not a Combination Product | 04/15/2020 | | |
| 5 | NDC:77136 - 500-05 | 18927.1 mL in 1 PAIL; Type 0: Not a Combination Product | 04/15/2020 | | |
| 6 | NDC:77136 - 500-55 | 208197.6 mL in 1 DRUM; Type 0: Not a Combination Product | 04/15/2020 | | |
| 7 | NDC:77136 - 500-75 | 1040988.2 mL in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: Not a Combination Product | 04/15/2020 | | |

| Marketing Information | | | |
|-------------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph not final | part333A | 04/15/2020 | |
| | | | |

Labeler - Midland Products LLC (138382226)

| Establishment | | | | |
|----------------------|---------|-----------|--|--|
| Name | Address | ID/FEI | Business Operations | |
| Midland Products LLC | | 138382226 | manufacture(77136-500), label(77136-500) | |

Revised: 4/2020 Midland Products LLC